Claims

We claim:

1. A powder for oral suspension, comprising:
   a) non-dihydrate azithromycin; and
   b) an azithromycin conversion stabilizing excipient.

2. The powder for oral suspension of Claim 1 wherein the azithromycin conversion stabilizing excipient is a viscosifying agent.

3. The powder for oral suspension of Claim 2 wherein the viscosifying agent is selected from the group consisting of a sugar, hydric alcohol and a polymer.

4. The powder for oral suspension of Claim 3 wherein the sugar is selected from the group consisting of sucrose, glucose, dextrose, maltose and fructose.

5. The powder for oral suspension of Claim 3 wherein the hydric alcohol is selected from the group consisting of sorbitol, mannitol, xylitol and maltitol.

6. The powder for oral suspension of Claim 3 wherein the polymer is selected from the group consisting of xanthan gum, guar gum, sodium alginate, carrageenan, hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose,

polyvinylpyrrolidone, maltodextrin, carbomer, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, carboxymethylcellulose, polydextrose and hydroxyethyl cellulose.

7. The powder for oral suspension of Claim 1 wherein the azithromycin conversion stabilizing excipient is a surface tension reducing excipient.

8. The powder for oral suspension of Claim 7 further comprising a conversion enhancer.

9. The powder for oral suspension of Claim 8 wherein the conversion enhancer is selected from the group consisting of a flavoring and a volatile organic component.

10. The powder for oral suspension of Claim 9 wherein the flavoring is selected from the group consisting of vanilla, grape, cherry, banana, and mixtures thereof.

11. The powder for oral suspension of Claim 9 wherein the volatile organic component is selected from the group consisting of 3-methyl-butyl acetate and isoamyl isovalerate.

12. The powder for oral suspension of Claim 9 wherein the azithromycin conversion stabilizing excipient is an anionic surfactant.

13. The powder for oral suspension of Claim 12 wherein the anionic surfactant is selected from the group consisting of sodium lauryl sulfate, sodium dioctyl sulfosuccinate and a bile salt.

14. The powder for oral suspension of Claim 9 wherein the azithromycin conversion stabilizing excipient is a surface active polymer.

15. The powder for oral suspension of Claim 14 wherein the surface active polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate succinate, hydroxypropyl cellulose and polyoxyethylene-polyoxypropylene copolymers.

16. The powder for oral suspension of Claim 9 wherein the azithromycin conversion stabilizing excipient is a non-ionic surfactant.

17. The powder for oral suspension of Claim 16 wherein the non-ionic surfactant is selected from the group consisting of a polysorbate, a nonylphenoxypolyoxyethylene, a polyoxyethylene ether and an octylphenol ethylene oxide.

18. The powder for oral suspension of Claim 1 further comprising at least one flavoring.

19. The powder for oral suspension of Claim 18 wherein the flavoring is selected from the group consisting of vanilla, grape, cherry, banana, and mixtures thereof.

20. The powder for oral suspension of Claims 1-19 wherein the non-dihydrate azithromycin is selected from the group consisting of forms B, D, E, F, G, H, M, N, O, P, Q, R, and mixtures thereof.

21. The powder for oral suspension of Claim 20 further comprising a non-viscosifying sweetener.

22. The powder for oral suspension of Claim 21 wherein the non-viscosifying sweetener is selected from the group consisting of saccharin, aspartame, acesulfame potassium, thaumatin and monelin.

23. The powder for oral suspension of Claims 1-19 wherein the non-dihydrate azithromycin comprises an ethanol solvate of azithromycin.

24. The powder for oral suspension of Claim 23 further comprising a non-viscosifying sweetener.

25. The powder for oral suspension of Claim 24 wherein the non-viscosifying sweetener is selected from the group consisting of saccharin, aspartame, acesulfame potassium, thaumatin and monelin.

26. The powder for oral suspension of Claims 1-19 wherein the non-dihydrate azithromycin comprises an isopropanol solvate of azithromycin.

27. The powder for oral suspension of Claim 26 further comprising a non-viscosifying sweetener.

28. The powder for oral suspension of Claim 27 wherein the non-viscosifying sweetener is selected from the group consisting of saccharin, aspartame, acesulfame potassium, thaumatin and monelin.

29. An oral suspension, comprising:
a) non-dihydrate azithromycin;
b) an azithromycin conversion stabilizing excipient; and
c) an aqueous vehicle.

30. The oral suspension of Claim 29 wherein the azithromycin conversion stabilizing excipient is a viscosifying agent.

31. The oral suspension of Claim 30 wherein the viscosifying agent is selected from the group consisting of a sugar, hydric alcohol and a polymer.

32. The oral suspension of Claim 31 wherein the sugar is selected from the group consisting of sucrose, glucose, dextrose, maltose and fructose.

33. The oral suspension of Claim 32 wherein the hydric alcohol is selected from the group consisting of sorbitol, mannitol, xylitol and maltitol.

34. The oral suspension of Claim 33 wherein the polymer is selected from the group consisting of xanthan gum, guar gum, sodium alginate, carrageenan, hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, polyvinylpyrrolidone, maltodextrin, carbomer, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, carboxymethylcellulose, polydextrose and hydroxyethyl cellulose.

35. The oral suspension of Claim 29 wherein the azithromycin conversion stabilizing excipient is a surface tension reducing excipient.

36. The oral suspension of Claim 35 further comprising a conversion enhancer.

37. The oral suspension of Claim 36 wherein the conversion enhancer is selected from the group consisting of a flavoring and a volatile organic component.

38. The oral suspension of Claim 37 wherein the flavoring is selected from the group consisting of vanilla, grape, cherry, banana, and mixtures thereof.

39. The oral suspension of Claim 37 wherein the volatile organic component is selected from the group consisting of 3-methyl-butyl acetate and isoamyl isovalerate.

40. The oral suspension of Claim 37 wherein the azithromycin conversion stabilizing excipient is an anionic surfactant.

41. The oral suspension of Claim 40 wherein the anionic surfactant is selected from the group consisting of sodium lauryl sulfate, sodium dioctyl sulfosuccinate and a bile salt.

42. The oral suspension of Claim 37 wherein the azithromycin conversion stabilizing excipient is a surface active polymer.

43. The oral suspension of Claim 42 wherein the surface active polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate succinate, hydroxypropyl cellulose and polyoxyethylene-polyoxypropylene copolymers.

44. The oral suspension of Claim 37 wherein the azithromycin conversion stabilizing excipient is a non-ionic surfactant.

45. The oral suspension of Claim 44 wherein the non-ionic surfactant is selected from the group consisting of a polysorbate,

nonylphenoxypolyoxyethylene, a polyoxyethylene ether and an octylphenol ethylene oxide.

46. The oral suspension of Claim 29 further comprising at least one flavoring.

47. The oral suspension of Claim 46 wherein the flavoring is selected from the group consisting of vanilla, grape, cherry, banana, and mixtures thereof.

48. The oral suspension of Claims 29-47 wherein the non-dihydrate azithromycin is selected from the group consisting of forms B, D, E, F, G, H, M, N, O, P, Q, R, and mixtures thereof.

49. The oral suspension of Claim 48 further comprising a non-viscosifying sweetener.

50. The oral suspension of Claim 49 wherein the non-viscosifying sweetener is selected from the group consisting of saccharin, aspartame, acesulfame potassium, thaumatin and monelin.

51. The oral suspension of Claims 29-47 wherein the non-dihydrate azithromycin comprises an ethanol solvate of azithromycin.

52. The oral suspension of Claim 51 further comprising a non-viscosifying sweetener.

53. The oral suspension of Claim 52 wherein the non-viscosifying sweetener is selected from the group consisting of saccharin, aspartame, acesulfame potassium, thaumatin and monelin.

54. The oral suspension of Claims 29-47 wherein the non-dihydrate azithromycin comprises an isopropanol solvate of azithromycin.

55. The oral suspension of Claim 54 further comprising a non-viscosifying sweetener.

56. The oral suspension of Claim 55 wherein the non-viscosifying sweetener is selected from the group consisting of saccharin, aspartame, acesulfame potassium, thaumatin and monelin.

57. A method for reducing the conversion of a form of non-dihydrate azithromycin in an oral suspension, by mixing an amount of a surface tension reducing excipient with a volume of an aqueous vehicle to form said suspension, wherein said amount of surface tension reducing excipient would lower the surface tension of a volume of water, equal to said volume of the aqueous vehicle, to below 50 dynes/cm.

58. A method of Claim 57 wherein the amount of the surface tension reducing excipient reduces the surface tension of the water below 40 dynes/cm.

59. The method of Claim 58 wherein the surface tension reducing excipient is an anionic surfactant.

60. The method of Claim 59 wherein the anionic surfactant is selected from the group consisting of sodium lauryl sulfate, sodium dioctyl sulfosuccinate and a bile salt.

61. The method of Claim 58 wherein the surface tension reducing excipient is a non-ionic surfactant.

62. The method of Claim 61 wherein the non-ionic surfactant is selected from the group consisting of a polysorbate, a nonylphenoxypolyoxyethylene, a polyoxyethylene ether and an octylphenol ethylene oxide.

63. The method of Claim 58 wherein the surface tension reducing excipient is a surface active polymer.

64. The method of Claim 63 wherein the surface active polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate succinate, hydroxypropyl cellulose and polyoxyethylene-polyoxypropylene copolymers.

65. The method of Claims 57-64 wherein the non-dihydrate azithromycin is selected from the group consisting of forms B, D, E, F, G, H, M, N, O, P, Q, R, and mixtures thereof.

66. The method of Claims 57-64 wherein the non-dihydrate azithromycin comprises an ethanol solvate of azithromycin.

67. The method of Claims 57-64 wherein the non-dihydrate azithromycin comprises an isopropanol solvate of azithromycin.

68. A method for reducing the conversion of a form of a non-dihydrate azithromycin in an oral suspension, wherein said oral suspension does not contain a conversion enhancer, by mixing a viscosifying agent with an aqueous vehicle and the non-dihydrate azithromycin to form said oral suspension having a viscosity of about 3 centipoise or more.

69. The method of Claim 68 wherein the viscosity of the oral suspension is about 40 centipoise or more.

70. The method of Claim 68 wherein the oral suspension is unflavored.

71. The method of Claims 68-70 wherein the viscosifying agent is selected from the group consisting of a sugar, hydric alcohol and a polymer.

72. The method of Claim 71 wherein the sugar is selected from the group consisting of sucrose, glucose, dextrose, maltose and fructose.

73. The method of Claim 71 wherein the hydric alcohol is selected from the group consisting of sorbitol, mannitol, xylitol and maltitol.

74. The method of Claim 71 wherein the polymer is selected from the group consisting of xanthan gum, guar gum, sodium alginate, carrageenan hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, polyvinylpyrrolidone, maltodextrin, carbomer, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, carboxymethylcellulose, polydextrose and hydroxyethyl cellulose.

75. A method for reducing the conversion of a form of non-dihydrate azithromycin, in an oral suspension, wherein said oral suspension contains a conversion enhancer, by reducing the viscosity of the oral suspension at room temperature to about 1 centipoise or less.

76. A method for reducing the conversion of a form of non-dihydrate azithromycin, in an oral suspension, wherein the oral suspension contains a conversion enhancer, by administering the oral suspension to a patient in need thereof within a period of time after constituting the oral suspension so that the level of said azithromycin conversion is less than 10%.

77. A method of Claim 76 wherein the conversion enhancer comprises at least one flavoring.

78. A method of Claims 76-77 wherein the oral suspension is administered to the patient within about 1 hour after constituting the oral suspension.